

Dated: August 18, 1995.  
David P. Howekamp,  
*Acting Regional Administrator.*  
[FR Doc. 95-26455 Filed 10-24-95; 8:45 am]  
BILLING CODE 6560-50-M

#### 40 CFR Part 52

[IA-18-1-6984b; FRL-5303-8]

##### Approval and Promulgation of Implementation Plans; State of Iowa

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the state of Iowa for the purpose of establishing the requirements set forth in the EPA's General Conformity rule. In the final rules section of the Federal Register, the EPA is approving the state's SIP revision as a direct final rule without prior proposal, because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, the direct final rule will be withdrawn, and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

**DATES:** Comments on this proposed rule must be received in writing by November 24, 1995.

**ADDRESSES:** Comments may be mailed to Lisa V. Haugen, Environmental Protection Agency, Air Branch, 726 Minnesota Avenue, Kansas City, Kansas 66101.

**FOR FURTHER INFORMATION CONTACT:** Lisa V. Haugen at (913) 551-7877.

**SUPPLEMENTARY INFORMATION:** See the information provided in the direct final rule which is located in the rules section of the Federal Register.

Dated: September 6, 1995.  
William Rice,  
*Acting Regional Administrator.*  
[FR Doc. 95-26460 Filed 10-24-95; 8:45 am]  
BILLING CODE 6560-50-P

#### 40 CFR Part 52

[WA5-1-5539b; FRL-5309-2]

##### Approval and Promulgation of Implementation Plans: Washington

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Washington for the purpose of bringing about the attainment of the national ambient air quality standards (NAAQS) for particulate matter with an aerodynamic diameter less than or equal to a nominal 10 micrometers (PM-10). The implementation plan was submitted by the State to satisfy certain Federal requirements for an approvable moderate nonattainment area PM-10 SIP for Tacoma, Washington. In the Final Rules Section of this Federal Register, the EPA is approving the State's SIP revision as a direct final rule without prior proposal because the Agency views this as a noncontroversial revision amendment and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this proposed rule, no further activity is contemplated in relation to this rule. If the EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA does not plan to institute a second comment period on this action.

**DATES:** Comments on this proposed rule must be received in writing by November 24, 1995.

**ADDRESSES:** Written comments should be addressed to Montel Livingston, SIP Manager, Environmental Protection Specialist (AT-082), Air and Radiation Branch, at the EPA Regional Office listed below. Copies of the documents relevant to this proposed rule are available for public inspection during normal business hours at the following locations. The interested persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day.

U.S. Environmental Protection Agency, Region 10, Air and Radiation Branch, 1200 6th Avenue, Seattle, WA 98101.  
The State of Washington, 4450 Third Avenue S.E., Lacey, Washington 98504.

**FOR FURTHER INFORMATION CONTACT:** Claire Hong, Air Programs Branch (AT-

082), EPA, 1200 6th Avenue, Seattle, WA 98101, (206) 553-1813.

**SUPPLEMENTARY INFORMATION:** See the information provided in the Direct Final action which is located in the Rules Section of this Federal Register.

Dated: September 22, 1995.  
Charles Findley,  
*Acting Regional Administrator.*  
[FR Doc. 95-26465 Filed 10-24-95; 8:45 am]  
BILLING CODE 6560-50-P

#### 40 CFR Part 180

[PP 3E4230/P634; FRL-4981-7]

RIN 2070-AC18

##### Jojoba Oil; Exemption from Tolerance Requirement

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** EPA proposes to establish an exemption from the requirement for a tolerance for residues of jojoba oil in or on all raw agricultural commodities when applied at not more than 1.0% of the final spray as an insecticide or as a pesticide spray tank adjuvant in accordance with good agricultural practices. Amvac Chemical Corp. submitted a petition pursuant to the Federal Food, Drug and Cosmetic Act (FFDCA) requesting the proposed regulation to establish an exemption from the requirement of a tolerance.

**DATES:** Comments, identified by the document control number [PP 3E4230/P634], must be received on or before November 24, 1995.

**ADDRESSES:** By mail, submit written comments to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address

given above, from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PP 3E4230/P634]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this proposed rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

**FOR FURTHER INFORMATION CONTACT:** By mail: Michael L. Mendelsohn, Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7501W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: 5th Floor, CS #1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8715; e-mail: mendelsohn.michael@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** Amvac Chemical Corp., 2110 Davie Ave., City of Commerce, CA 90040, has submitted pesticide petition (PP) 3E4230 to EPA proposing to amend 40 CFR part 180 by establishing a regulation pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to exempt from the requirement of a tolerance simmondsia liquid wax (jojoba oil) and the product Detur for use as an inert ingredient in pesticide formulations applied to growing crops or to raw agricultural commodities after harvest. Subsequent to its petition, Amvac informed EPA that it had transferred all Detur assets to Imperial Jojoba Oils of El Centro, CA. EPA has, of its own initiative, expanded the original petition to include pesticidal uses of jojoba oil in this proposed exemption from the requirement of a tolerance.

The data submitted in the petition and all other relevant material have been evaluated and a discussion of the submitted data and literature referenced follows.

The source of jojoba oil is the *Simmondsia chinensis* shrub, commonly called the jojoba plant. The plant is a woody evergreen shrub, 2 to 3 feet high with thick, leathery, bluish-

green leaves and dark brown, nutlike fruit. Two techniques are used to release the oil from the plant fruit (also called a nut, bean, or seed). The oil may be extracted by pressing or by solvent extraction methods used commercially to isolate vegetable oils. The expressed oil is clear and golden in color.

The exact composition of the oil varies dependent upon geographic location of the plant and can vary from bean to bean within a single plant. Jojoba oil is composed almost completely of wax esters of monounsaturated, straight-chain acids and alcohols with high molecular weights ( $C_{16}$ - $C_{26}$ ). Jojoba oil has been defined as a liquid wax ester with the generic formula  $RCOOR'$ . RCO represents oleic acid, eicosanoic acid ( $C_{20}:1$ ), and/or erucic acid ( $C_{22}:1$ ) moieties. -OR' represents eicosenyl alcohol ( $C_{20}:1$ ), docosenyl alcohol ( $C_{22}:1$ ) and/or tetrasenyl alcohol ( $C_{24}:1$ ) moieties. Crude jojoba oil contains 0.8 ppm elemental lead (Pb) and less than 0.1 ppm arsenic ( $As_2S_3$ ).

The jojoba bean contains 2 glycosides with toxic effects: simmondsin [2-(cyanomethylene)-3-hydroxy-4,5-dimethoxycyclohexyl-D-glucoside] at 2.3% and simmondsin-2'-ferulate at 1% (Verbiscar and Banigan, 1978. *J. Ag. Fd. Chem.* 26:1456-60). In addition, related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin are present (Abbott, T.P., Nakamura, L.K., "Microbial Detoxification of Jojoba Toxins," Agricultural Research Service, 1990). As set forth below, this proposed exemption does not cover these ingredients, and they are therefore not permitted to be present in the jojoba oil subject to this exemption. A third toxic component which makes up to 14% of jojoba oil is erucic acid. Erucic acid is also found in rapeseed oil in amounts up to 50% ("The Chemistry and Technology of Jojoba Oil" by James Wisniak). The amount of erucic acid likely to be present in residues of jojoba oil under this exemption is less than 1/10 of the amount (2%) permitted in rapeseed oil defined by FDA as low erucic acid rapeseed oil.

#### Toxicology

EPA's evaluation of the toxicological properties of jojoba oil is based in part upon numerous toxicology studies conducted both for the purposes of evaluating the use of jojoba oil in cosmetic products and as a pesticide. In addition, the Agency took into consideration the fact that jojoba oil has been widely distributed in commerce and available to the general public throughout the United States for

cosmetic uses without any evidence of significant adverse effects to humans or the environment.

Chronic data was not deemed necessary to support the proposed exemption because of the low application levels allowed and the fact that most of the jojoba oil ingested orally is excreted in the feces (Yaron, A. "Metabolism and Physiological Effects of Jojoba Oil" in *The Chemistry and Technology of Jojoba Oil*, 1987, Wisniak, J.). The expected dietary exposure to humans as a result of the use of this substance as an inert or active pesticide ingredient applied at 1% of the final spray is far below levels that produced no adverse effects in laboratory animals.

As noted above, formulations of jojoba oil may contain erucic acid and the glycosides simmondsin and simmondsin-2'-ferulate (as well as related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin), ingredients which are of toxicological concern.

Erucic acid, which has been identified as a potential contributing factor in heart disease, makes up approximately 14% of jojoba oil. However, this proposed exemption only exempts residues resulting from the application of a final spray diluted to no more than 1% jojoba oil, the level of erucic acid in the spray applied to raw agricultural commodities will fall from 14% to 0.14%. This is less than one-tenth the 2% erucic acid level permitted for low erucic acid rapeseed oil (see FDA regulations at 21 CFR 184.1555(c)), and therefore does not pose a hazard to human health.

The Agency lacks sufficient information to conclude that simmondsin and simmondsin-2'-ferulate as well as related conjugated organonitriles including demethyl simmondsin and didemethylsimmondsin would not cause adverse health effects when applied under the terms of this proposed exemption. For this reason, the proposed exemption only applies to formulations of jojoba oil not containing simmondsin and simmondsin-2'-ferulate.

A summary of the the available toxicological data for simmondsin, simmondsin-2'-ferulate, erucic acid, and jojoba oil is set forth below.

#### A. *Simmondsin and Simmondsin-2'-Ferulate*

Simmondsin and/or its breakdown products have been linked to diet rejection or restriction in rats (Booth, A.N., C.A. Elliger, A.J. Waiss, 1974. "Isolation of a Toxic Factor from Jojoba Meal," *Life Sci.* 15:1115).

Ingested Simmondsin, a glycoside in jojoba bean, caused rats to avoid food. Administration of 6,000 ppm of simmondsin in the diet of rats produced a 24% body weight decrease. Twenty percent of mice fed with 10% simmondsin in the diet died within 1 week (Letter from Andrew Laumbach (FDA) to Don Barioni (Jojoba Oil Oils, CA) dated July 8, 1992). (Letter from Karen Korman to Don Barioni dated July 22, 1992).

When weanling rats were given simmondsin orally for 5 days at 750 mg/kg/day, all rats lost weight and died within 10 days (R.K. Locke, FDA memo 3/22/78).

A dose of 2.5 g/kg simmondsin orally did not decrease body weight in rats (Khalsa, J.H. FDA memo May 27, 1983; R.K. Locke, FDA memo 3/22/78).

A dose of 3.6 g/kg simmondsin by i.p. injection had no effect on rats' body weight (Khalsa, J.H. FDA memo May 27, 1983; R.K. Locke, FDA memo 3/22/78).

A single oral dose of 4 g/kg of simmondsin to weanling rats produced no effects during a 14-day observation (Khalsa, J.H. FDA memo May 27, 1983; R.K. Locke, FDA memo 3/22/78).

A diet containing 0.6% of Simmondsin produced weight loss in rats as did a diet containing 10% jojoba oil (Locke, R.K. to L.J. Lin, FDA memo 3/22/78).

#### B. Erucic Acid

Erucic acid (13%) in jojoba oil may contribute to heart disease. Nestle Technical Product Assistance-Orbe, Switzerland.

Jojoba oil contains 14% of erucic acid which has been shown to cause myocardial fibrosis (Abdullatif, A.M.M. and E.O Vles, 1971. *Nutr. Metabol.* 13:63-74).

#### C. Jojoba Oil Acute Oral Toxicity Studies

Fewer than 50% of rats died when orally administered 21.5 mL/kg of jojoba oil (Wisniak, J., 1977, "Jojoba Oil and Derivatives." *Proc. Chem. Fats and Lipids* 15(3):167-218.). Four groups (10 males and 10 females/group) rats were orally administered 0.5, 0.75, 1.13 and 1.69 mL/10 g of crude jojoba oil. After 7 days, rats were killed and necropsied. One rat died before the end of the 7 days; renal capsule discoloration was noted in all groups; peritonitis was noted in one 1.69 mL/10g group (Taguchi, M. and Kunitomo, 1977. "Toxicity Studies on Jojoba Oil for Cosmetic Uses," *Cosmetics Toiletries*, 19:53-62 (September issue). CS (RP)).

The oral LD<sub>50</sub> for crude jojoba oil in mice is greater than 1.69 mL/10 g. No death or clinical signs were noted

(Taguchi, Masayuki, 1990. "Test Results on Safety on Jojoba oil to be Used for Cosmetics" in *La Jojoba*, Apache Junction, AZ; p 149-170.).

Four groups (10 males and 10 females/group) of rats were fed basal diet (5g/feeding containing 0.5, 1.0, 2.0, and 3.0 g of refined jojoba oil. The first two groups were dosed for 7 days, and the last two groups were dosed for 4 days. Signs of toxicity were noted in five rats in the 1.0-g group and six rats each in the 2.0-g and 3.0-g groups. One rat died in each of the 1.0-, 2.0-, and 3.0-g dose groups (Hamm, D. J., 1984.

"Preparation and Evaluation of Trailkoxyltricarballate, Trialhoxycitrate, Trailkoxylglycerylether, Jojoba Oil and Sucrose Polyester as Low calories Replacements of edible Fats and Oils" *J. of Food Science* (49):419-428). (OW) Twenty percent of weanling mice died when fed a diet with 10% jojoba oil (Locke, R.K. to L.J. Lin, FDA memo, 3/22/1978).

A single oral administration at 5,050 mg/kg of DETUR (a pesticide product containing 97.5% jojoba oil) to HSD:SD rats did not produce death in any animal. The oral LD<sub>50</sub> for DETUR in HSD:SD rats is greater than 5,050 mg/kg body weight which is classified as toxicity category IV for pesticide precautionary labeling purposes.

In the testing of a lip balm product containing 20% jojoba oil, none of the rats (5 males and 5 females) died when orally administered with 5.0 g/kg of 20% jojoba oil (lip balm product) (CTFA, 1985. CIR Safety Data Test Summary Response Form. Acute oral toxicity study on lip balm product containing 20% jojoba oil, 1 p.)

#### Acute Dermal Toxicity Studies

A single dose of 2,020 mg/kg of DETUR (a pesticide product containing 97.5% jojoba oil) was topically applied to the shaved intact skin of 5 male and 5 female rabbits for 24 hours and treated rabbits were observed for 14 days. No mortality was noted; transient skin irritation and diarrhea were noted; one female had mottled liver. The acute dermal LD<sub>50</sub> of DETUR is greater than 2,020 mg/kg body weight and classified as Toxicity category III for pesticide precautionary labeling purposes.

#### Primary Eye Irritation Studies

Instillation of refined Jojoba Oil (0.1 mL) into the eyes of six male rabbits produced slight blepharitis and slight conjunctival hyperemia at 1 hour after instillation. All signs cleared by 24 hours post-instillation (Taguchi, M. and Kunitomo, 1977. "Toxicity Studies on Jojoba Oil for Cosmetic Uses," *Cosmetics Toiletries*, 19:53-62

(September issue). CS (RP) Instillation of lip balm product containing 20% of jojoba oil (0.1 mL) into the eyes of six rabbits produced eye irritation score of 0.3 ± 0.8 (Draize scale) at 24 hours post-instillation. All reactions were cleared at 48 hours post-instillation (CTFA, 1985 as reported in Diener, Robert M. ed., 1992. "Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax." Nineteenth Report of the Cosmetic Ingredient Review Expert Panel. *J. American College of Toxicology*, Vol. 11(1):57-82).

Administration of DETUR (a pesticide product containing 97.5% jojoba oil) into rabbit eyes caused positive conjunctival irritation in rabbits for 48 hours. DETUR is considered to be a mild eye irritant and is classified as EPA toxicity category III for precautionary labeling purposes.

#### Primary Dermal Irritation Studies

Refined jojoba oil (0.5 mL) as well as olive oil and light liquid paraffin (0.5 mL) serving as controls were topically applied to the shaved skin of three groups of 5 guinea pigs daily for 15 days. The same procedure was conducted in the other three groups of 5 guinea pigs daily for 30 days. A Draize scoring system was used. No significant reactions to jojoba oil and olive oil were noted. Flare reactions to liquid paraffin were noted on the third day of the study (Taguchi, M. and Kunitomo, 1977.

"Toxicity Studies on Jojoba Oil for Cosmetic Uses." *Cosmetics Toiletries*, 19:53-62 (September issue)). CS (RP).

Jojoba oil (10.0% w/w in refined Jojoba oil) was topically applied to albino marmots according to Draize method. No skin reactions were noted in any animals (Taguchi, Masayuki, 1990. "Test Results on Safety on Jojoba oil to be Used for Cosmetics" in *La Jojoba*, Apache Junction, AZ; p. 149-170.).

A topical application of lip balm product containing 20% jojoba oil to New Zealand white rabbits produced a primary irritation score of 0.33—minimally irritating (CTFA, 1985 as reported in Diener, Robert M., ed., 1992. "Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax. Nineteenth Report of the Cosmetic Ingredient Review Expert Panel." *J. American College of Toxicology*, Vol. 11(1): 57-82.).

Application of 0.5 mL of DETUR (a pesticide product containing 97.5% jojoba oil) on the shaved dorsal skin of 6 rabbits did not produce deaths or other signs of systemic toxicity. Transient erythema/eschar formation was seen in two males and two females. Within 24 hours all treated skin sites were normal. The primary dermal

irritation index was 0.17. DETUR is considered to be slightly irritating and in EPA's toxicity category IV for precautionary labeling purposes.

#### Dermal Sensitization Studies

The skin sensitization potential of jojoba alcohol (10.0% w/w in refined Jojoba oil) was evaluated according to the maximization test using albino marmots (10 males and 10 females). Two groups of marmots (10 males and 10 females) were used as the controls. No sensitization reaction was observed 24 or 48 hours after the challenge application (Taguchi, Masayuki, 1990. "Test Results on Safety on Jojoba oil to be Used for Cosmetics." *La Jojoba*, Apache Junction, AZ; p. 149-170.).

Five out of six human subjects suspected to be sensitive to jojoba oil had positive reactions when patch tested with jojoba olive oil and jojoba oil-petrolatum mixtures. Twenty-eight human subjects with no known sensitivities did not have sensitization reactions to pure jojoba oil (Scott, M.J. and M.J. Scott, Jr., 1982, "Jojoba Oil," *J. Am. Acad. Dermatology* 6(4):545.).

The skin irritation and sensitization test of lip balm product containing 20% jojoba oil in humans produced no skin sensitization and irritation (CTFA, 1988, as reported in Diener, Robert M., ed., 1992. "Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax. Nineteenth Report of the Cosmetic Ingredient Review Expert Panel." *J. American College of Toxicology*, Vol. 11(1): 57-82.).

The skin irritation and sensitization test of topical product containing 10% jojoba oil was conducted in humans using the Draize-Shelanski repeat insult patch test. No skin sensitization or irritation was evident (CTFA, 1988 as reported in Diener, Robert M., ed., 1992. "Final Report on the Safety Assessment of Jojoba Oil and Jojoba Wax. Nineteenth Report of the Cosmetic Ingredient Review Expert Panel." *J. American College of Toxicology*, Vol. 11(1): 57-82.).

#### 90-Day Feeding Toxicity Study in Rodents and Dogs

Jojoba oil incorporated in the diet of rat at 0.5, 5.0, and 10.0% (w/w) for 2 months produced elevations of transaminase and alkaline phosphatase at weeks 4 and 13 of the study period. Nestle Product Technical Assistance - Orbe, Switzerland (n.d)

#### Metabolism and Absorption Studies

##### *Effects of Ingestion of Jojoba Oil on Blood Cholesterol Levels and Lipoprotein Patterns in New Zealand White Rabbits*

This study was conducted to determine the cholesterol-lowering effect of crude jojoba if fed to animals. Six groups (4 per group) of New Zealand White Rabbits were fed for 30 days with various combination of basal diet mixed with cholesterol, jojoba oil, and safflower. Blood cholesterol was then determined. Two or six percent crude jojoba oil added to the atherogenic diet containing 1% cholesterol resulted in a 40% reduction of blood cholesterol as compared to cholesterol control rabbits. Under the same conditions, 2% safflower oil was not effective in lowering blood cholesterol levels. The authors suggested that jojoba oil was absorbed across the intestinal mucosa, contrary to the hypothesis that it is totally excreted and not metabolized (Clarke, J.A. and D.M. Yermanos, 1981. "Effects of Ingestion of Jojoba Oil on Blood Cholesterol Levels and Lipoprotein Patterns in New Zealand White Rabbits." *Biochemical and Biophysical Research Communication* 102(4):1409-1415).

##### *Preparation and Evaluation of Trailkoxycitricarballylate, Trialkoxycitrate, Trailkoxylglycerylether, Jojoba Oil, and Sucrose Polyester as Low Calories Replacements of Edible Fats and Oils*

This study evaluated the digestibility and caloric availability of test oils including refined jojoba oil. Crude jojoba oil was refined by a standard alkali refining process which is used to refine edible vegetable oils. In the refined jojoba oil, free fatty acids were reduced to 0.023% from 1.45% in the crude oil. A trace nitrogen level of  $6 \pm 2$  ppm was found in the refined oil which translated to an upper limit of  $160 \pm 54$  ppm of Simmondsin in the finished oil. Simmondsin and/or its breakdown products have been linked with the diet rejection or restriction in rats. Four groups of 10 Sprague-Dawley rats each were fed with 0.5, 1.0, 2.0, and 3.0 grams of refined jojoba oil once a day for 7 consecutive days. Feces were collected, weighed and then the percentages of water, ash, fat, protein, and carbohydrate were analyzed. No diet rejection was noted in any dose group. Weakness and depression were noted in 50% of 1.0-g dosed rats and in all 2.0- and 3.0-gms dosed rats; one rat in each of these dose groups died during the study. Jojoba oil was poorly absorbed and resistant to digestion, but

anal leakage was noted. Jojoba oil can act as a laxative and interfere with certain vitamin and mineral absorption from the gut. (Hamm, D. J., 1984. "Preparation and Evaluation of Trailkoxycitricarballylate, Trialkoxycitrate, Trailkoxylglycerylether, Jojoba Oil and Sucrose Polyester as Low calories Replacements of Edible Fats and Oils," *J. of Food Science* (49):419-428). (OW)

#### Conclusion

The Agency estimates that the dietary exposure to humans from jojoba oil when applied in accordance with the limitations set forth in this proposed exemption is far below the levels that produced no adverse effects in laboratory animals. For this reason, and upon review of its use, EPA has determined that jojoba oil, when used in accordance with good agricultural practices is useful and poses no hazard to the public health. Accordingly, EPA proposes to exempt jojoba oil from the requirements of a tolerance under the conditions set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended, which contains any of the ingredients listed herein, may request within 30 days after publication of this notice in the Federal Register that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the FFDCA.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating the document control number, [PP 3E4230/P634]. All written comments filed in response to this petition will be available in the Public Response and Program Resources Branch, at the address given above from 8 a.m. to 4:30 p.m., Monday through Friday, except legal holidays.

A record has been established for this rulemaking under docket number [PP 3E4230/P634] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2,

1921 Jefferson Davis Highway,  
Arlington, VA.

Electronic comments can be sent  
directly to EPA at:  
opp-Docket@epamail.epa.gov

Electronic comments must be  
submitted as an ASCII file avoiding the  
use of special characters and any form  
of encryption.

The official record for this  
rulemaking, as well as the public  
version, as described above will be kept  
in paper form. Accordingly, EPA will  
transfer all comments received  
electronically into printed, paper form  
as they are received and will place the  
paper copies in the official rulemaking  
record which will also include all  
comments submitted directly in writing.  
The official rulemaking record is the  
paper record maintained at the address  
in "ADDRESSES" at the beginning of  
this document.

Under Executive Order 12866 (58 FR  
51735, Oct. 4, 1993), the Agency must  
determine whether the regulatory action  
is "significant" and therefore subject to  
all the requirements of the Executive  
Order (i.e., Regulatory Impact Analysis,  
review by the Office of Management and  
Budget (OMB)). Under section 3(f), the  
order defines "significant" as those  
actions likely to lead to a rule (1) having  
an annual effect on the economy of \$100  
million or more, or adversely and  
materially affecting a sector of the  
economy, productivity, competition,  
jobs, the environment, public health or  
safety, or State, local or tribal  
governments or communities (also  
known as "economically significant");  
(2) creating serious inconsistency or  
otherwise interfering with an action  
taken or planned by another agency; (3)  
materially altering the budgetary  
impacts of entitlement, grants, user fees,  
or loan programs; or (4) raising novel  
legal or policy issues arising out of legal  
mandates, the President's priorities, or  
the principles set forth in this Executive  
Order.

Pursuant to the terms of this  
Executive Order, EPA has determined  
that this rule is not "significant" and is  
therefore not subject to OMB review.

Pursuant to the requirements of the  
Regulatory Flexibility Act (Pub. L. 96-  
354, 94 Stat. 1164, 5 U.S.C. 601-612),  
the Administrator has determined that  
regulations establishing new tolerances  
or raising tolerance levels or  
establishing exemptions from tolerance  
requirements do not have a significant  
economic impact on a substantial  
number of small entities. A certification  
statement to this effect was published in  
the Federal Register of May 4, 1981 (46  
FR 24950).

This proposed rule contains no  
Federal mandates under Title II of the  
Unfunded Mandates Reform Act of  
1995. Pub. L. 104-4 for State, local, or  
tribal governments or the private sector  
because it would not impose  
enforceable duties on them.

#### List of Subjects in 40 CFR Part 180

Environmental protection,  
Administrative practice and procedure,  
Agricultural commodities, Pesticides  
and pests, Reporting and recordkeeping  
requirements.

Dated: September 29, 1995.

Janet L. Andersen,  
*Acting Director, Biopesticides and Pollution  
Prevention Division, Office of Pesticide  
Programs.*

Therefore, it is proposed that 40 CFR  
part 180 be amended as follows:

#### PART 180—[AMENDED]

1. The authority citation for part 180  
continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new  
§ 180.1160, to read as follows:

#### § 180.1160 Jojoba oil; exemption from the requirement of a tolerance.

The insecticide and spray tank  
adjuvant jojoba oil is exempted from the  
requirement of a tolerance in or on all  
raw agricultural commodities when  
applied at the rate of 1.0% or less of the  
final spray in accordance with good  
agricultural practices, provided the  
jojoba oil does not contain simmondsin,  
simmondsin-2-ferulate and related  
conjugated organonitriles including  
demethyl simmondsin and  
didemethylsimmondsin.

[FR Doc. 95-26325 Filed 10-24-95; 8:45 am]  
BILLING CODE 6560-50-F

#### 40 CFR Part 180

[OPP-300399; FRL-4981-2]

RIN 2070-AC18

#### Octadecanoic Acid, 12-Hydroxy-, Homopolymer, Octadecanoate; Tolerance Exemption

AGENCY: Environmental Protection  
Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes to  
establish an exemption from the  
requirement of a tolerance for residues  
of octadecanoic acid, 12-hydroxy-,  
homopolymer, octadecanoate (CAS Reg.  
No. 58128-22-6) when used as an inert  
ingredient (surfactant and dispersing

agent) in pesticide formulations applied  
to growing crops or to raw agricultural  
commodities after harvest, under 40  
CFR 180.1001(c). ICI Americas, Inc.,  
requested this proposed regulation  
pursuant to the Federal Food, Drug and  
Cosmetic Act (FFDCA).

DATES: Written comments, identified by  
the document control number [OPP-  
300399], must be received on or before  
November 24, 1995.

ADDRESSES: By mail, submit written  
comments to Public Response and  
Program Resources Branch, Field  
Operations Division (7506C), Office of  
Pesticide Programs, Environmental  
Protection Agency, 401 M St., SW.,  
Washington, DC 20460. In person,  
deliver comments to: Rm. 1132, CM #2,  
1921 Jefferson Davis Hwy., Arlington,  
VA 22202. Information submitted as a  
comment concerning this document  
may be claimed confidential by marking  
any part or all of that information as  
"Confidential Business Information"  
(CBI). Information so marked will not be  
disclosed except in accordance with  
procedures set forth in 40 CFR part 2.  
A copy of the comment that does not  
contain CBI must be submitted for  
inclusion in the public record.  
Information not marked confidential  
will be included in the public docket by  
EPA without prior notice. All written  
comments will be available for public  
inspection in Rm. 1132 at the address  
given above, from 8 a.m. to 4:30 p.m.,  
Monday through Friday, excluding legal  
holidays.

Comments and data may also be  
submitted electronically by sending  
electronic mail (e-mail) to: opp-  
docket@epamail.epa.gov. Electronic  
comments must be submitted as an  
ASCII file avoiding the use of special  
characters and any form of encryption.  
Comments and data will also be  
accepted on disks in WordPerfect in 5.1  
file format or ASCII file format. All  
comments and data in electronic form  
must be identified by the docket number  
[OPP-300399]. No Confidential Business  
Information (CBI) should be submitted  
through e-mail. Electronic comments on  
this proposed rule may be filed online  
at many Federal Depository Libraries.  
Additional information on electronic  
submissions can be found below in this  
document.

FOR FURTHER INFORMATION CONTACT: By  
mail: Rita Kumar, Registration Support  
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Environmental Protection Agency, 401  
M St., SW., Washington, DC 20460.  
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